IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION	**MDL No. 2804**
This document relates to: *Track One Cases*	**Case No. 17-md-2804**
	Hon. Dan Aaron Polster

BRIEF IN SUPPORT OF TEVA AND ACTAVIS GENERIC DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

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I. INTRODUCTION

Cephalon, Inc. ("Cephalon") and Teva Pharmaceuticals USA, Inc. ("Teva USA") present this Court with a very different situation—one that compels summary judgment in their favor on all claims.[1] The companies have only promoted two specialized branded Schedule II opioid medicines (Actiq and Fentora). Both medications are unique. Both are FDA-approved for treating cancer patients suffering from breakthrough pain—sharp spikes of severe pain that break through the relief provided by the patient's existing opioid medications. Both are indicated only for opioid-tolerant patients—patients who already have been taking opioids to treat their pain. And both are short-acting—they provide immediate, tailored relief to address the breakthrough pain. Thus, Actiq and Fentora share little in common with the long-acting opioid medicines designed to treat long-term chronic pain that Plaintiffs contend are the "driving force" of the opioid abuse crisis.[2]

In addition, because of their specific indication and potency, Actiq and Fentora have long been subject to unique FDA-mandated risk mitigation programs. Those programs ensure that prescribing doctors, their patients, pharmacists, and distributors are informed of the risks, labeled indications, and proper administration of these products. Not surprisingly, given their narrow indication, Actiq and Fentora are not widely prescribed—they reflect less than .03% of all opioid prescriptions in Cuyahoga and Summit Counties (the "Counties") from 2006 to 2016. For example, in 2016, there were 0 prescriptions of either Actiq or Fentora in Summit County, and just 20 prescriptions of Fentora in Cuyahoga County (and no Actiq prescriptions).

The Actavis Generic Defendants (who first became affiliated with the Teva Defendants in

[1] Cephalon and Teva USA are referred to as the "Teva Defendants." Watson Laboratories, Inc., Actavis LLC, Actavis Pharma, Inc., Warner Chilcott Company, LLC, Actavis South Atlantic LLC, Actavis Elizabeth LLC, Actavis Mid Atlantic LLC, Actavis Totowa LLC, Actavis Kadian LLC, Actavis Laboratories UT, Inc. f/k/a Watson Laboratories, Inc.-Salt Lake City, and Actavis Laboratories FL, Inc., f/k/a Watson Laboratories, Inc.-Florida are collectively referred to as the "Actavis Generic Defendants."

[2] *See, e.g.*, Ex. 12, M. Schumacher Report, ¶ 58.

2016) also present a very different situation—which, likewise, compels summary judgment in their favor. They did not promote the safety or efficacy of their opioid medicines in Ohio or elsewhere.[3] And like the Teva Defendants, the Actavis Generic Defendants complied with all suspicious order monitoring and reporting requirements. Further, they sold quantities of opioids within the production quotas set by the DEA as necessary to meet the legitimate therapeutic needs of the country.[4] As a matter of law, the Teva and Actavis Generic Defendants cannot be held liable for ***lawfully*** selling ***lawful*** products in ***lawful*** amounts, regardless of any unlawful conduct by others.

Notwithstanding these uncontroverted facts, Plaintiffs seek to impose liability on the Teva and Actavis Generic Defendants (the "Moving Defendants") for the tragic abuse of prescription and illicit opioids in the Counties. All of Plaintiffs' claims fall under two overarching theories of liability—that Defendants: (1) falsely marketed opioids to physicians;[5] and (2) failed to identify, report and stop shipment of suspicious orders.[6] But while Plaintiffs chose ***to plead*** these claims by lumping together all manufacturers, opioid medicines, and prescriptions, Plaintiffs cannot ***prove*** them in the aggregate. As a matter of law (and basic due process), Plaintiffs must provide individualized proof that ***each Defendant*** engaged in wrongdoing that caused Plaintiffs a cognizable harm.[7] The factual record shows there is ***no*** such proof as to the Moving Defendants.

False Marketing Claims. Plaintiffs' false marketing theory fails for the simple reason that

[3] The Actavis Generic Defendants have filed a separate motion for summary judgment ("Generic MSJ"), together with other generic manufacturers, explaining that the false marketing claims against them and Teva USA (prior to 2011) fail because they: (a) sold only generic medicines and did not promote them; (b) any failure to warn claims are preempted; and (c) they cannot be held responsible for the allegedly fraudulent conduct of others and for merely selling their FDA-approved medicines. (ECF No. 1749.)

[4] To the extent Plaintiffs contend that some Defendants defrauded the DEA into setting inappropriate quotas, there is no evidence that any Teva or Actavis Generic Defendant did so, and such claims would be preempted in any event as set forth in Manufacturers' Joint Motion for Summary Judgment on Preemption (ECF No. 1760).

[5] Summit 3AC ¶¶ 227, 345, 393, 424; Cuyahoga 3AC ¶¶ 215, 333, 381, 412.

[6] Summit 3AC ¶¶ 493–525; Cuyahoga 3AC ¶¶ 480–509.

[7] *See* Manufacturers' Memorandum of Law in Support of Motion for Summary Judgment for Plaintiffs' Failure to Offer Proof of Causation ("Causation Brief") (ECF No. 1771).

there is no evidence that the Moving Defendants engaged in any false marketing. Plaintiffs have failed to adduce any evidence of false statements made to physicians regarding Actiq and Fentora. And although Plaintiffs also try to blame the Teva Defendants for various cherry-picked statements in third-party publications by organizations that received some funding by Cephalon (and none of the other Moving Defendants), the uncontroverted evidence establishes that those third parties independently created their publications, and signed agreements specifying that Cephalon did not control the content of what they said or wrote. Further, the undisputed record shows that Actavis Generic Defendants did not promote their products, much less do so falsely.

Plaintiffs also have no evidence of causation: they have ***no testimony*** from a ***single*** Ohio prescriber showing that he or she was misled by any statement or omission attributable to any of the Teva or Actavis Generic Defendants into writing a ***single*** opioid prescription—much less one that was medically inappropriate. To the contrary, they could not have been misled as to Actiq or Fentora. Throughout the limitation period, prescribers have had to comply with the stringent requirements of a heightened FDA-mandated Risk Evaluation and Mitigation Strategy ("TIRF REMS Program") ***before*** writing a prescription for Actiq or Fentora. Each doctor must pass a knowledge test about the risks of these medicines, review the FDA-approved medication guides for Actiq and Fentora with the patient, and sign an agreement (with the patient) that she understands and has counseled her patient about the risks and approved uses of Actiq and Fentora.

Plaintiffs also cannot show a cognizable injury—a necessary element of each of their claims. Plaintiffs ***concede*** that they have no evidence of a single Ohio resident harmed by any prescription of Actiq, Fentora, or any other opioid sold by the Moving Defendants.

Suspicious Order Monitoring Claims. Plaintiffs assert that the Moving Defendants had a duty to identify, report, and stop allegedly "suspicious" opioid orders placed by pharmacies in

Ohio. But pharmacies purchase opioid medicines ***from distributors***—not manufacturers. There is no requirement in any law or agency guidance requiring manufacturers to identify, report, or refuse orders placed by their customers' customers (the pharmacies), as opposed to the manufacturer's customers (the distributors). Testimony from DEA agents and Plaintiffs' own experts confirm this. Instead, as common sense would dictate, distributors are the ones who must have procedures in place to monitor the purchases of ***their customers***.

Regardless, there is no evidence that any alleged duty was violated. Neither Plaintiffs nor their experts have adduced a single shred of evidence showing that a single order (for an opioid shipment into the Counties) placed with the Moving Defendants was "suspicious," should have been reported or stopped, or resulted in any actual diversion. In fact, Plaintiffs have not come forward with a shred of evidence to show that ***any*** order filled by the Moving Defendants (for an opioid shipment into the Counties) was diverted, abused, caused anyone to become addicted, infringed a public right, or caused Plaintiffs to incur some expense.

On this record, summary judgment is required.

II. BACKGROUND

A. The Moving Defendants.

Cephalon manufactures and sells two branded products: Actiq and Fentora. (Summit 3AC, ¶ 70; Cuyahoga 3AC, ¶ 63.) Cephalon began selling Actiq in 2001 and Fentora in 2006. (Ex. 5, 2000 SEC Form 10-k; Ex. 58, Fentora Approval Letter.) Teva USA first became affiliated with Cephalon in 2011. (Summit 3AC, ¶ 69; Cuyahoga 3AC, ¶ 62.) Before then, Teva USA sold only generic opioid medicines, but has never promoted their safety or efficacy. (Ex. 54, C. Beader Decl., ¶¶ 3–4.) Cephalon and Teva USA are separate, indirect subsidiaries of Teva Pharmaceutical Industries Ltd. ("Teva Ltd."). (Ex. 56, H. West Decl., ¶ 6.) Teva Ltd. is an Israeli corporation that

has never marketed, distributed, or manufactured opioids anywhere, let alone in Ohio.[8] (*Id.*, ¶ 2–3; Ex. 3, D. Herman Dep., 196:1–4.)

The Actavis Generic Defendants became affiliated with Teva USA in August 2016. (Summit 3AC, ¶ 69; Cuyahoga 3AC, ¶ 50.) The Actavis Generic Defendants likewise have never promoted the safety or efficacy of their generic opioid medicines. (Ex. 4, M. Perfetto Dep., 315:18–19; *id.* 316:13–317:1; Ex. 57, D. Myers Decl., ¶ 4; Exs. 1–2; Generic MSJ, ECF No. 1749.)

B. The Teva Defendants Only Promoted Two Short-Acting Opioid Medicines—Actiq and Fentora.

Actiq is a unique short-acting prescription opioid approved by the FDA for the "management of breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain." (Ex. 59, Actiq Label.) The package insert (label) for Actiq, which is provided to every patient to whom it is prescribed, has always included explicit safety and risk warnings—and pre-dating the limitation period (October 27, 2012 to the present), a boxed warning. That warning discloses the risks of abuse, addiction, overdose, and death. (*Id.*) Cephalon promoted Actiq from 2001 to 2006—and not since. (Ex. 5; Ex. 6, at TEVA_MDL_A_00283253.)

Cephalon obtained approval for Fentora in 2006. (Ex. 58, Approval Letter.) Fentora is also a short-acting opioid indicated to treat "breakthrough pain in patients with cancer" who are opioid tolerant. (Ex. 7, Fentora Label.) The package insert for Fentora also comes with extensive risk disclosures, including a boxed warning that warns of abuse, addiction, overdose, and death. (*Id.*) Like Actiq, Cephalon no longer promotes Fentora. (Ex. 8, J. Hassler Dep., 43:22–44:1.)

Because of their unique indications, Actiq and Fentora are rarely prescribed. (*See* Ex. 9,

[8] Teva Ltd. has challenged personal jurisdiction and moved to dismiss all claims against it. (ECF No. 1264.) That motion remains pending. In any event, Plaintiffs have alleged ***no independent*** conduct against Teva Ltd., and summary judgment in its favor is appropriate for the same reasons.

S. Nicholson Report, ¶ 13; *id.*, Ex. 1.) They represent less than .03% of all opioids prescribed in Cuyahoga and Summit Counties since 2006. (*Id.*, ¶ 43.) Indeed, there have been years in which no prescription for either drug was written in either County. (*Id.*, ¶ 42 (citing IMS/Exponent data).)

C. Throughout The Limitation Period, Prescribers And Patients Had To Certify Awareness Of The Risks And Unique Indications Of Actiq And Fentora.

Since March 2012, prescribers choosing to prescribe Actiq or Fentora—and patients choosing to take them—have had to comply with the stringent requirements of the TIRF REMS Program before a prescription of these medicines can be dispensed. *See* 21 U.S.C. § 355-1 (governing REMS programs); Ex. 10, TIRF REMS Program; Ex. 11, E. Michna Report, ¶¶ 68–87.) For prescribing physicians, these requirements include:

- ***Knowledge Test***. Each prescriber must review educational materials and successfully pass a knowledge assessment ***before being eligible to prescribe*** Actiq and Fentora. (Ex. 10, TIRF REMS Program ¶ II(B)(1)(b)(i); *see also id.* at 51–53.) The prescriber must certify that she understands the "***responsible use conditions for TIRF medicines and the risks and benefits of chronic opioid therapy.***" (Ex. 10, TIRF REMS Program ¶ II(B)(1)(b)(i). (emphases added).)

- ***Patient-Provider Agreement***. Both patient and prescriber must sign a TIRF REMS Patient-Prescriber Agreement Form ("Patient Agreement") before the patient's first prescription. (*Id.*, ¶ II(B)(1)(b)(ii).) The Patient Agreement requires patient and prescriber to acknowledge that they each understand the risks, consequences, and approved uses of TIRF medicines; indeed, the prescriber must expressly certify that she has "counseled [the] patient or their caregiver about ***the risks, benefits, and appropriate use of the TIRF medicine***." (*Id.*; *see also id.* at 54–56.)

- ***Medication Guide***. An FDA-approved medication guide must be provided to the patient before the medication is dispensed. *See* 21 C.F.R. § 208.24 (imposing requirement); Ex. 10, TIRF REMS Program ¶ II(A). The medication guide conveys the approved indications, the contra-indications, and the FDA-approved risk language—which makes clear that TIRF medicines can put patients at risk for addiction, abuse, misuse, overdose, and death, even when used properly. (*Id.*)

Distributors and pharmacists also must adhere to TIRF REMS Program requirements designed to prevent diversion, and to ensure their full familiarity with the risks and appropriate uses of these medications. (Ex. 11, E. Michna Report, ¶¶ 70–71.) Plaintiffs have failed to adduce any evidence

that anyone failed to comply with these requirements with regard to Actiq or Fentora.

D. Plaintiffs Have Not Identified Any False Or Misleading Statements By The Moving Defendants.

None of Plaintiffs' alleged marketing experts identify any false statements by the Moving Defendants, much less any such statements related to Ohio or which misled Ohio prescribers. Indeed, two of Plaintiffs' experts do not even mention the Moving Defendants. (Ex. 12, M. Schumacher Dep., 84:17–14; *id.* 103:6–105:11 (stating that he cannot identify any false statements made by Moving Defendants and "do[es] not have evidence for these companies"); Ex. 13, A. Lembke Dep., 391:16-396:6 (no reference to Moving Defendants in Appendix I of report, which purports to identify misleading statements by Defendants).) Another of Plaintiffs' marketing experts was simply told to assume all marketing was false. (Ex. 14, M. Perri Report, ¶ 154.)

E. Plaintiffs Rely Upon Allegations Of Off-Label Promotion And A Plea Agreement Regarding Cephalon Conduct In 2001.

Rather than coming forward with any evidence of false or misleading statements, Plaintiffs rely upon the fact that, in 2008, Cephalon (not Teva USA) pled guilty to a misdemeanor for the off-label promotion of Actiq (and other non-opioid medicines) during an eight-month period ***in 2001***.[9] This is more than a decade ***prior*** to the longest potential limitation period.[10] Further, the plea only involved off-label promotion. There was no allegation or admission of any false marketing. It is well-settled that off-label promotion is not inherently "false or misleading," *United States v. Caronia*, 703 F.3d 149, 165 (2d Cir. 2012), and may be protected by the First Amendment. *Id.* at 169; *see also Sorrell v. IMS Health Inc.*, 564 U.S. 552, 557 (2011).

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[9] *See* Ex. 49, Plea Agreement, at ¶ (A)(8). Dr. Kessler, for instance, opines that Cephalon engaged in off-label promotion, but fails to connect any promotion to Ohio and addresses no conduct after 2008. (Ex. 15, D. Kessler Report, ¶ 474 (Actiq); *id.*, ¶ 493 (Fentora).) Similarly, Dr. Egilman opines about the Cephalon plea agreement, but he did not review and analyze even a single off-label statement. (Ex. 16, D. Egilman Report, § 7.27; Ex. 17, D. Egilman Dep., Apr. 24, 2019, 231:6–12.)

[10] Moving Defendants filed a partial summary judgment motion based upon the applicable statutes of limitations, which, at a minimum, bar claims based upon any alleged conduct prior to October 27, 2012. (ECF No. 1691.)

F. The Teva Defendants Have Long Operated One Of The Most Robust Compliance Programs In The Industry.

Prior to and during the relevant limitations period, Cephalon and Teva followed stringent marketing safeguards designed to ensure full compliance with all applicable laws and regulations related to the promotion and sale of their products. (Ex. 54, P. Glover Decl., ¶¶ 4-7.) Cephalon enacted significant compliance policies and procedures to ensure the truthful and on-label promotion of their products, and the appropriate and legally compliant use of key opinion leaders and grants to third parties.[11] Internal committees reviewed and approved promotional materials pertaining to Actiq and Fentora prior to use.[12] Any reported violations were investigated and, where appropriate, the Company took disciplinary measures.[13] In 2007, Cephalon hired the former Pennsylvania Attorney General (and now U.S. District Court Judge) Gerald Pappert as its General Counsel, and a federal health care prosecutor as its Chief Compliance Officer.[14]

As a result of the very 2008 misdemeanor plea cited by Plaintiffs, Cephalon entered into a five-year Corporate Integrity Agreement ("CIA")—which resulted in further enhancements to its compliance program, procedures, and committees. (Ex. 8, J. Hassler Dep., 703:18–706:15; Ex. 19, M. Day Dep., 50:20–51:14; Ex. 18, H. Dorfman Report, ¶¶ 71–83.) Independent companies were retained to conduct comprehensive audits of Cephalon's compliance programs and marketing during the CIA period (from 2008 to 2012), including with respect to promotional messaging. (Ex. 18, H. Dorfman Report, ¶¶ 89–91.) Cephalon passed each audit. (*Id.*, ¶ 84.) Annual reports were submitted to the Office of Inspector General ("OIG") detailing the company's compliance efforts. Each year, the OIG found those legal compliance efforts sufficient.[15]

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[11] *See* Ex. 18, H. Dorfman Report, ¶¶ 32–70.
[12] *Id.*, ¶¶ 36–38.
[13] *Id.*, ¶¶ 59–63.
[14] *Id.*, ¶¶ 70.
[15] *See, e.g.*, Ex. 21, TEVA_MDL_A_11891302; Ex. 22, TEVA_MDL_A_00782034.

In early 2012, all of the Cephalon compliance policies were integrated with those of Teva USA. (Ex. 54, P. Glover Decl., ¶¶ 4-5.) As a result, Cephalon and Teva USA have had one of the most robust compliance programs in the industry throughout the limitations period. There is no evidence of any false, misleading, or even off-label marketing in Ohio during that time. (*Id.* ¶ 4.).

G. The Teva Defendants Did Not Control Any Third Party Statements.

Since long before the limitation period, Cephalon had policies in place to ensure the independence of all CMEs and medical education programs;[16] it did not direct the content of these programs or any third-party publications. (Ex. 8, J. Hassler Dep., 322:18–323:10.) Indeed, contracts to provide funding to these third party organizations made independence an express condition of the funding.[17] There is no evidence that these policies were not followed. On the contrary, every "key opinion leader" deposed to date has testified that the Teva Defendants did not influence the content of any of their programs or publications.[18]

H. The Moving Defendants Complied With DEA Regulations.

The DEA—the entity responsible for regulating all opioid medicine production and distribution—has full visibility into the market. (Ex. 30, K. Wright Dep., 170:2–14.) The DEA sets different types of quotas (individual production and manufacturing quotas) based on the Attorney General's determination of the total quantity and production quotas for Scheduled

[16] *See* Ex. 23, US Policy205-Independent Medical Education Grants (August 2012), TEVA_MDL_A_00560932; Ex. 24, Independent Medical Education Grants Policy (January 26, 2009), TEVA_MDL_A_00785735; Ex. 25, C–126 Cephalon Policy on Company Giving (July 2008), TEVA_MDL_A_00785338; Ex. 26, Cephalon Policy on Third–Party Grant Requests (January 2008), TEVA_MDL_A_00553027; Ex. 27, Marketing Policy on Grants, Effective June 2007, TEVA_MDL_A_00552919.

[17] *See, e.g.*, Ex. 28, Independent Educational Program Grant Agreement with AAPM, TEVA_MDL_A_01169010 (Nov. 28, 2006) (Section 8(b) provides that "neither Cephalon nor its agents shall control the content of the Program"); Ex. 29, Independent Educational Program Grant Agreement with MediCom Worldwide, Inc., TEVA_MDL_A_00502973 (Nov. 6, 2008) (Section 7(a) provides that "neither Cephalon nor its agents shall control the content of the Program").

[18] Ex. 31, R. Portenoy Dep., Jan. 24, 2019, 475:20–476:25; *id.* at 331:6–25; *id.* at 464:10–465:1; 467:25–468:6; *id.* 398:17–400:13; Ex. 32, L. Webster Dep., Feb. 18, 2019, 299:15–300:10; *id.* 375:7–17; *id.* 223:4–7; Ex. 33, S. Fishman Dep., Feb. 26, 2019, 293:8–294:2; *id.* 80:10–82:6.

substances nationwide. 21 U.S.C. § 826(a)–(c). The Moving Defendants have always complied with DEA quotas, which reflect an assessment not only of the overall market, but also of the Moving Defendants' business.[19] Plaintiffs have failed to adduce any evidence to the contrary.

The DEA also requires registrants to "design and operate a system to disclose to the registrant suspicious orders of controlled substances."[20] DEA witnesses confirm that there has never been an obligation for pharmaceutical manufacturers to: (1) report orders placed with other companies (*i.e.*, orders placed by pharmacies with distributors); (2) have a particular SOM system in place; and (3) maintain written SOM policies.[21]

The Moving Defendants always have had systems in place to flag and investigate potentially suspicious orders placed with them. (Ex. 39, C. McGinn Dep., 225:10–227:11; Ex. 40 at ALLERGAN_MDL_02128514; Ex. 41, M. Woods Dep., 31:3–32:5; *id.*, 53:9–22.) And the DEA has never taken any enforcement action against the Teva or Actavis Generic Defendants. (Ex. 38, K. Colder Report, 34 n.97.) Neither Plaintiffs nor their experts have identified a single order for opioid medicines placed with the Moving Defendants that they contend was "suspicious."

III. ALL FALSE MARKETING CLAIMS (COUNTS I, III, AND V–X) FAIL.

A. Plaintiffs Have No Evidence Of Any False Marketing By The Teva Defendants In Cuyahoga Or Summit County.

To succeed on their false marketing claims,[22] Plaintiffs must provide evidence of actual

[19] *See* 21 U.S.C. § 826(C) ("In fixing such quotas, the Attorney General shall determine the manufacturer's estimated disposal, inventory, and other requirements. . ."); *see also* Ex. 34, S. Harper-Avilla Dep., Apr. 11, 2019, 44:5–25.
[20] 21 C.F.R. § 1301.74(b).
[21] *See* Ex. 35, T. Prevoznik Dep., 326:1–5, 358:21-359:1; Ex. 36, J. Rafalski Dep., 655:14–17; Ex. 37, L. Holifield Report, p. 5, ¶ 3(c), (d) ("The only requirements related to 'suspicious orders' under the regulations is that a registrant must implement a system to identify and report suspicious orders' to DEA" and "[t]he regulations do not state that a registrant must investigate 'suspicious orders' or halt them prior to shipment"); Ex. 38, K. Colder Expert Report, p. 11 ("DEA did not provide meaningful guidance to registrants seeking more information on how to comply with their suspicious order monitoring obligations, leaving interpretation to the discretion of individual registrants.").
[22] Summit 3AC, ¶ 879 (Count I), ¶ 946 (Count III), ¶ 990 (Count V), ¶ 1001 (Count VI), ¶ 1047 (Count VII), ¶ 1074 (Count VIII), ¶ 1094 (Count IX), ¶ 1110 (Count X); Cuyahoga TAC ¶ 923 (Count I), ¶ 988 (Count III), ¶ 1031 (Count V), ¶ 1049 (Count VI), ¶ 1090 (Count VII), ¶ 1117 (Count VIII), ¶ 1137 (Count IX), ¶ 1152 (Count X).

misrepresentations or omissions by Cephalon and Teva USA. Plaintiffs, however, lack any evidence of a single false statement made by the Teva Defendants in Ohio—much less one that took place within the applicable limitation period (*i.e.*, at least since October 2012).

Apart from the lack of any evidence, Plaintiffs' accusation that the Teva Defendants engaged in a 20-year scheme to defraud ignores the undisputed facts. While Plaintiffs' experts contend that the "driving force of this national catastrophe has been the introduction and marketing of ***long-acting formulations*** of high-potency opioids,"[23] Teva Defendants did no such thing. They only promoted two ***short-acting*** opioids approved to treat breakthrough cancer pain.

Plaintiffs' reliance on Cephalon's long ago plea agreement for off-label promotion of Actiq (and not Fentora) during an eighth-month period in 2001—***more than 15 years before this case was filed***-—cannot support their fraudulent marketing claims or forestall summary judgment. There is no evidence that any off-label marketing occurred in Ohio, much less within the applicable limitations period. (Ex. 54, P. Glover Decl., ¶ 4.) Regardless, off-label marketing is not inherently "false or misleading." *Caronia*, 703 F.3d at 165; *In re Actimmune Mktg. Litig*., 614 F. Supp. 2d 1037, 1051 n.6 (N.D. Cal. 2009) ("[O]ff-label marketing of an approved drug is itself not inherently fraudulent."). For this very reason, courts have rejected similar fraud-based claims against the Teva Defendants based upon identical allegations of off-label promotion.[24]

Plaintiffs also seek to hold the Teva Defendants liable for statements made by third parties partially funded by Cephalon.[25] To do so, Plaintiffs must establish an agency relationship between each Teva Defendant and each third party, *see McWilliams v. S.E., Inc.*, 581 F. Supp. 2d 885, 893

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[23] Ex. 12, Schumacher Report, at ¶ 58.

[24] *See Travelers Indem. Co. v. Cephalon, Inc.*, 32 F. Supp. 3d 538, 552 (E.D. Pa. 2014), *aff'd*, 620 F. App'x 82 (3d Cir. 2015); *Ind./Ky./Ohio Reg'l Council of Carpenters Welfare Fund v. Cephalon, Inc.*, No. 13-7167, 2014 WL 2115498, at *5–7 (E.D. Pa. May 21, 2014); *Cent. Reg'l Emps. Ben. Fund v. Cephalon, Inc.* ("*CREB II*"), No. 09-3418 MLC, 2010 WL 1257790 (D.N.J. Mar. 29, 2010); *Cent. Reg'l Emps. Ben. Fund v. Cephalon, Inc.* ("*CREB I*"), No. 09-3418 MLC, 2009 WL 3245485 (D.N.J. Oct. 7, 2009).

[25] Summit TAC, ¶ 171; Cuyahoga TAC, ¶ 204.

(N.D. Ohio 2008), including the "right of control" by the principal. *Taylor v. Checkrite, Ltd.*, 627 F. Supp. 415, 416–17 (S.D. Ohio 1986). Here, there is no evidence whatsoever that the Teva Defendants exercised any "right of control" over any third-party organization or "key opinion leader"—much less any of their publications.

The evidence, in fact, proves the contrary: third-party organizations operated independently of, and were not influenced by any funding from, the Teva Defendants. (Ex. 42, S. Beckhardt Dep., 37:7–37:15; *id.*, 43:11–43:21; *id.*, 254:23–255:7; *id.*, 367:5–367:16; *id.*, 370:21–371:2.)[26] For instance, while Cephalon provided unrestricted education grants for third-party organizations to use for publications and CMEs, the contracts at issue expressly provided that "neither Cephalon nor its agents shall control the content of the Program."[27] That is exactly what happened. (Ex. 8, J. Hassler Dep., 322:18–3:10; *id.*, 326:13–327:5.)

Similarly, Plaintiffs accuse the Teva Defendants of spreading misrepresentation through "key opinion leaders," like Drs. Portenoy, Fishman, and Webster. However, those witnesses testified that they developed their opinions free of influence by the Teva Defendants.[28]

B. Plaintiffs Lack Any Evidence To Show That Any Marketing By The Teva Defendants Caused Them Any Harm.

Causation is an element of Plaintiffs' claims.[29] As set forth in the Causation Brief,

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[26] *See also Batzel v. Smith*, 333 F.3d 1018, 1036 (9th Cir. 2003); *Protostorm, LLC v. Antonelli, Terry, Stout & Krous, LLP*, 834 F. Supp. 2d 141, 162 (E.D.N.Y. 2011).

[27] *See* Ex. 42, S. Beckhardt Dep., Feb. 1, 2019, 37:7–37:15; *id.*, 43:11–43:21; id., 254:23–255:7; *id.*, 367:5–367:16; id., 370:21–371:2; *see also, e.g.*, Ex. 28, TEVA_MDL_A_01169010 (Nov. 28, 2006) (Section 8(b) provides that "neither Cephalon nor its agents shall control the content of the Program"); Ex. 29, TEVA_MDL_A_00502973 (Nov. 6, 2008) (Section 7(a) provides that "neither Cephalon nor its agents shall control the content of the Program").

[28] Ex. 31, R. Portenoy Dep., 475:20–476:25; *id.* at 331:6–25; *id.* at 464:10–465:1; 467:25–468:6; *id.* 398:17–400:13; Ex. 32, L. Webster Dep., 299:15–300:10; *id.* 375:7–17; *id.* 223:4–7; Ex. 33, S. Fishman Dep., Feb. 26, 2019, 293:8–294:2; *id.* 80:10–82:6; Ex. 43, TEVA_MDL_A_01088845.

[29] *See In re ClassicStar Mare Lease Litig.*, 727 F.3d 473, 487 (6th Cir. 2013) (but for and proximate causation are elements of a RICO claim); *Berisford v. Sells*, 331 N.E.2d 408, 409 (Ohio 1975) (actual and proximate causation are elements of a negligence claim); *City of Cincinnati v. Deutsche Bank Nat'l Tr. Co.*, 863 F.3d 474 (6th Cir. 2017) (In Ohio, actual and proximate cause are elements for common law public nuisance); *City of Cleveland*, 615 F.3d 496, 503 (6th Cir. 2010) (actual and proximate causation apply to Plaintiffs' OCPA claims).

Plaintiffs cannot simply lump all Defendants together; they must show that "the conduct of ***each defendant*** was a substantial factor in producing the harm." *Pang v. Minch*, 559 N.E.2d 1313, 1324 (Ohio 1990) (citation omitted, emphasis added); *see also Holmes v. Sec. Investor Prot. Corp.*, 503 U.S. 258, 268 (1992).

But after a year of discovery, Plaintiffs still cannot identify a ***single*** Ohio prescriber who received and then relied upon any allegedly false marketing by the Teva Defendants to write a medically inappropriate prescription, as opposed to exercising her own independent medical judgment.[30] Plaintiffs, in fact, have ***no*** testimony from a single Ohio doctor. Nor can they ***assume*** that all Ohio prescribers who interacted with sales representatives for the Teva Defendants were misled, given that prescribers write prescriptions for a variety of reasons ***other than marketing***, such as insurance coverage, prior experience, and individual patient characteristics. (Ex. 44, P. Chintagunta Report, ¶¶ 41–49; Ex. 45, M. Rosenblatt Report, ¶ 55; *see also Travelers Indem. Co. v. Cephalon, Inc.*, 620 F. App'x 82, 87 (3d Cir. 2015) ("allegations that physicians attended presentations and interacted with Cephalon sales representatives do not sufficiently demonstrate that these interactions *caused* the physicians to write the prescriptions at issue").

In fact, Plaintiffs ***cannot*** show causation as to the Teva Defendants, given the TIRF REMS Program and its stringent requirements. How could a prescriber be misled about the safety risks or efficacy of Actiq or Fentora when she had to first pass an FDA-approved test on these very issues, sign a Patient Agreement confirming such awareness, and certify in writing that she "counseled [the] patient . . . about ***the risks, benefits, and appropriate use of the TIRF medicine***"? (Ex. 46.) This alone breaks the chain of causation.

Unable to show causation, Plaintiffs have turned to multiple regression models that rely

[30] Ohio doctors must be aware of the labels and risks of the medicines that they prescribe, and must evaluate the individualized risks for each patient prescribed an opioid medicine. Ohio Admin. Code Ch. 4731-29-01.

upon aggregate proof about the supposed impact of all detailing by opioid manufacturers regardless of content (false or not), product, or whether the manufacturer is a defendant in this case. This approach is legally flawed. *See, e.g.*, *In re Bextra & Celebrex Mktg. Sales Practices & Prod Liab. Litig.*, 2012 WL 3154957, at *7 (N.D. Cal. 2012) ("Because 'at least some doctors were not misled by Defendants' alleged misrepresentations . . . general proof of but-for causation is impossible.'" (quoting *UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121, 135 (2d Cir. 2010)). Regardless, their regression models fail to link any alleged injury to any misconduct by the Teva or Actavis Generic Defendants.[31] Indeed, Plaintiffs' modeling simply assumes the outcome; it fails to isolate any false marketing by any Teva Defendant, to apportion causation as to the Teva Defendants, or even to show how they supposedly caused any improper prescribing.

Lastly, even if Plaintiffs could tie a particular prescription to marketing by the Teva Defendants through one of their experts (which they cannot), Plaintiffs present no evidence that any such prescription was medically inappropriate, was diverted, or was misused or abused, in such a way as to cause any of the harms for which Plaintiffs seek relief. In short, Plaintiffs simply have no evidence of causation as to the Teva Defendants.

C. Plaintiffs Fail To Identify Any Injury Attributable To The Teva Defendants.

To survive summary judgment, Plaintiffs must identify a cognizable injury that resulted from the Teva Defendants' marketing of Actiq and Fentora.[32] They have not done so.

There is no evidence that any Ohio patient who took one of the Teva Defendants' opioid

[31] *See* Ex. 44, P. Chintagunta Report, ¶¶ 67–72 (Professor Rosenthal's modeling is insufficient to demonstrate that the Teva Defendants' promotional efforts for Actiq and Fentora increased sales of prescription opioids); Ex. 47, J. Ketcham Report & Errata, ¶¶ 178-180; *see also id.* ¶¶ 181-266 (Professor Rosenthal fails to establish a causal relationship between alleged promotion of opioids and opioid shipments); Ex. 9, S. Nicholson Report, ¶¶ 29–49 (Dr. Cutler's estimates of harms attributable to prescription opioid shipments are flawed).

[32] *See, e.g., Holmes v. Sec. Investor Prot. Corp.*, 502 U.S. 258, 268 (1992) (RICO); *City of Cleveland v. Ameriquest Mortg. Secs., Inc.*, 615 F.3d 496, 502 (6th Cir. 2010) (OCPA); *City of Cincinnati v. Deutsche Bank Nat'l Tr. Co.*, 863 F.3d 474, 480 (6th Cir. 2017) (public nuisance); *Berisford v. Sells*, 331 N.E.2d 408, 409 (Ohio 1975) (negligence); *Picklesimer v. Balt. & O. R. Co.*, 84 N.E.2d 214, 217 (Ohio 1949) (fraud).

medicines became addicted or suffered some other harm. Indeed, Plaintiffs concede that they have no such evidence because they "do ***not*** intend to assert . . . tha[t] any specific prescription was unauthorized, medically unnecessary, ineffective, ***or harmful***." (ECF No. 1058, at 4 (emphasis added).) Plaintiffs make no effort to trace any past or even potential future expenses to any specific prescriptions (or suspicious orders) of Actiq or Fentora—much less link any prescriptions to any false marketing. This complete failure to proof defeats Plaintiffs' claims.

Plaintiffs seem to contend that harm exists merely because individuals received off-label prescriptions of Actiq and Fentora in the Counties.[33] This argument fails. Both "[c]ourts and the FDA have recognized the propriety and potential public value of unapproved or off-label drug use." *Caronia*, 703 F.3d at 153.[34] The undisputed evidence shows that off-label Actiq or Fentora prescriptions can benefit patients. (Ex. 45, M. Rosenblatt Report, ¶¶ 37–52 (identifying examples); Ex. 11, E. Michna Report, ¶ 35 (same); Ex. 31, R. Portenoy Dep., 538:9:–19; Ex. 32, L. Webster Dep., 288:7–16.) And Plaintiffs have no evidence that any patients were harmed from any off-label prescription of Actiq or Fentora—much less that Plaintiffs incurred any downstream harm.

IV. THE SOM CLAIMS (COUNTS II, IV–VII, IX–XI) AGAINST THE MOVING DEFENDANTS FAIL.

Plaintiffs' SOM theory seeks to hold the Moving Defendants legally responsible for failing to identify, report, and stop suspicious orders.[35] But the record is devoid of any evidence to support

[33] *See* Ex. 49, Summit County's Am. Responses to Manufacturers' First Set of Interrogs., at No. 9 ("prescriptions for Actiq [and] Fentora. . . were prescribed to individuals who did not have a recent cancer diagnosis of cancer").

[34] *See also Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 351 n.5 (2001) (off-label prescribing "often is essential to giving patients optimal medical care"); Use of Approved Drugs for Unlabeled Indications, FDA Drug Bulletin, Vol. 12, No. 1, at 4–5 (Apr. 1982) ("accepted medical practice often includes drug use that is not reflected in approved drug labeling") (quoted in *Weaver v. Reagen*, 886 F.2d 194, 198 (8th Cir. 1989); Ex. 11, E. Michna Report, ¶ 36.

[35] Plaintiffs' RICO, nuisance, fraud, unjust enrichment, and civil conspiracy claims all rest upon this theory of liability predicated upon Manufacturers' SOM systems and reporting obligations. (Summit 3AC, ¶¶ 916, 921, 923, 929–33, 939, 959, 965–67, 986, 1012, 1046, 1054, 1056, 1059, 1062, 1103, 1126; Cuyahoga 3AC, ¶¶ 949, 963, 971–72, 999, 1007–09, 1027, 1053, 1062, 1085, 1089, 1097, 1099, 1105, 1168.)

those claims as to any of the Teva and Actavis Generic Defendants.

As a threshold matter, Plaintiffs argue that manufacturers should have identified, reported, and stopped orders ***placed by Ohio pharmacies***.[36] But as a general principle, manufacturers do not sell and ship opioids directly to pharmacies. (Ex. 9, S. Nicholson Report, ¶¶ 234–35.) Such orders are placed with distributors, which manufacturers rely upon to monitor their own customers. (*Id.*, ¶ 235.) And Plaintiffs identify no obligation under state or federal law to know and report orders placed by the customers (*i.e.*, pharmacies) of a manufacturer's customers (*i.e.*, distributors).

Even DEA executives could not point to any statute, regulation, formal notice, or correspondence communicating such a requirement.[37] Asked directly whether DEA "ever provided any kind of guidance to manufacturers informing them that they were to know their customers' customer," DEA representative Thomas Prevoznik flatly answered: "No, not to my knowledge."[38]

Regardless, Plaintiffs have no evidence of any breach of any diversion-related duty: Plaintiffs cannot identify a single order (for shipment into the Counties) connected to the Teva or Actavis Generic Defendants that was purportedly "suspicious." This glaring failure alone defeats their claims. In fact, only one of Plaintiffs' experts, Dr. Keller, purports to address this fundamental issue, yet she conceded that she could not identify any actual "suspicious" orders (as defined by DEA regulations)—only orders that she believes, after the fact, should have triggered further investigation. (L. Keller Dep., Jun. 13, 2019, 335:14–336:7; *id.* 336:12–16.) And to do that, she relied upon ***post-shipment*** data (chargeback and prescription data) pertaining to ***completed*** shipments to pharmacies and ***fulfilled prescriptions*** by physicians. (Ex. 52, L. Keller

[36] March 4, 2019 Pls.' Supplemental Rog Responses, at 310 ("Although Defendants have objected to Plaintiff's prior response to this Interrogatory as listing only transactions between distributors and pharmacists, Plaintiff contends that those are suspicious orders as to which Defendants had duties to report and to (attempt to) stop shipment").
[37] *See* Ex. 51, D. Ashley Dep., 159:20–161:8.
[38] *See* Ex. Ex. 35, T. Prevoznik Dep., 326:1–5.

Report, ¶¶ 32–33). Importantly, DEA representatives have made clear that there is no requirement to obtain and consider such data as part of any SOM program.[39]

Lastly, Plaintiffs cannot show causation: that any unreported "suspicious" orders placed with the Teva or Actavis Generic Defendants caused Plaintiffs' alleged harm. None of Plaintiffs' experts even attempt to link any fulfilled "suspicious" order by (or any order placed with) the Moving Defendants to any incident of addiction, crime, or overdose in the Counties—much less any expense incurred by Plaintiffs to address such problems. Nor do any of Plaintiffs' experts attempt to attribute any injury whatsoever to the Moving Defendants on this theory.

V. THE CLAIMS ARE BARRED BY THE APPLICABLE STATUTE OF LIMITATIONS.

As explained in the pending Motion For Partial Summary Judgment On Statute Of Limitations Grounds (ECF No. 1691), the longest limitations period for any of Plaintiffs' claims is five years. But there is no evidence of any wrongdoing by the Teva and Actavis Generic Defendants ***after October 27, 2012***. Plaintiffs have not adduced a single false statement made by the Teva or Actavis Generic Defendants during the limitation window. In fact, Cephalon stopped promoting Actiq in 2006, and the industry-leading safeguards of the TIRF REMS Program have been in place since March 2012. Accordingly, Plaintiffs' claims are time-barred.

VI. CONCLUSION

Summary judgment should be entered as to all claims against the Moving Defendants.

[39] *See* Ex. 30, K. Wright Dep., 220:20–221:3; *see also* Ex. 51, D. Ashley Dep., 172:20–173:12; *see also* Ex. 35, T. Prevoznik, 347:1–5; *see also* Ex. 53, J. Rannazzisi Dep., 120:6–21.

Dated: June 28, 2019

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on June 28, 2019, the Teva and Actavis Generic Defendants' Motion for Summary Judgment, along with the Memorandum of Law, proposed Order, exhibits, and summary fact sheet, were served via email on all attorneys of record consistent with the June 24, 2019 Order setting forth Directions Regarding Filing of Briefs Under Seal.

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